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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,813	04/20/2001	Robert Henry	54195-5001	3042

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[REDACTED] EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
1638	47

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/839,813	HENRY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stuart Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 22-42 is/are pending in the application.  
 4a) Of the above claim(s) 32-42 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 22-31 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____	6) <input type="checkbox"/> Other: ____

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Applicant's election without traverse of Group I claims 22-31 in Paper No. 6 is acknowledged.

The specification is objected to because claimed priority is not stated. Applicant should amend the first line of the specification (37 CFR 1.78) to indicate the claimed priority.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The inventors claim a recipient plant cell or tissue produced by a method of transferring a gene into a plant comprising transforming a recipient plant cell by microprojectile bombardment with DNA isolated from a donor plant and a recipient plant cell or tissue transformed by said method. The Applicants do not identify or describe the genes that have been transformed into the recipient cell, the characteristic structural features inherent to the genes that were transformed into the recipient cell nor the phenotype of the recipient cell. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of

an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Given the lack of genetic and phenotypic description for the recipient plant cell, it remains unclear what features identify the recipient plant cell or tissue. Since the inventors have not described the genetics and phenotype of the newly transformed cells, the specification fails to provide an adequate written description to support the claimed material.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hadi et al (1996 Plant Cell Reports 15:500-505).

The claims are drawn to a method of transferring a gene into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor wherein the DNA is high molecular weight genomic DNA from a different species of plant than the recipient plant. Included in the transformation is a selection construct.

Hadi et al teach a method of transforming soybean using microprojectile bombardment with high molecular weight DNA directly isolated from maize including a plasmid that confers

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resistance to the antibiotic hygromycin-B (see page 501, for example). The teachings of Hadi anticipate the claimed invention.

Claims 22-23, 26-28, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Christou (1997 Plant Molecular Biology 35:197-203).

The claims are drawn to a method of transferring a gene into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant, wherein said donor plant and said recipient plant are members of different genera and different species and the recipient cell is of the species *Oryza sativa*. The claims are also drawn to a transformed recipient plant cell.

Christou teaches methods of rice transformation using microprojectile bombardment wherein DNA directly isolated from barley is transformed into rice and in another example more than one gene is transformed into rice (page 201, left column). The teachings of Christou anticipate the claimed invention.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christou (1997 Plant Molecular Biology 35:197-203) and Hadi et al (1996 Plant Cell Reports 15:500-505) taken with Weining et al (1991 Theor Appl Genet 82: 209-216) and further in view of Applicants' admitted state of the prior art.

The claims are drawn to a method of transferring a gene into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant, wherein said donor plant and said recipient plant are members of different genera and different species wherein both are members of a cereal and the recipient cell is of the species *Oryza sativa*. The claims are also drawn to a transformed recipient plant cell.

Hadi et al teach a method of transforming soybean using microprojectile bombardment with high molecular weight DNA from maize including a plasmid that confers resistance to the antibiotic hygromycin-B.

Hadi et al do not teach isolating high molecular weight DNA from a cereal nor transforming rice with the high molecular weight DNA using microprojectile bombardment.

Christou teaches a method of transforming *Oryza* using microprojectile bombardment wherein the DNA is high molecular weight DNA isolated from a species of plant other than *Oryza*.

Weining et al teaches isolating high molecular weight DNA from a wide range of cereal crops.

Applicants' admitted state of the prior art teaches (page 18, lines 17-19 "Wild members of *Oryzae* have been shown to be important sources of genes for improvement of yield". The method of Weining et al would be applicable to wild rice species including *Zizania*.

Given the recognition of those of ordinary skill in the art of the value of transforming plants via microprojectile bombardment and of using a selection construct as taught by Hadi et al, and the value of producing a rice plant transformed by microprojectile bombardment as taught by Christou, it would have been obvious to modify this method by transforming rice plants with

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high molecular weight DNA isolated from a cereal as taught by Weining et al for the purpose of introducing more than one gene into the rice genome to improve the rice gene pool. One would be motivated to isolate and transform other plant species with DNA from *Zizania* given applicants admitted statement that wild members of *Oryzae* would be good sources of genetic material to be introduced into rice plants for improvement of yield.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 25, and 28 and all subsequent dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is indefinite and unclear for reciting “a gene” wherein the definition of “directly isolated DNA” as reported in the specification (page 8, 1<sup>st</sup> paragraph) is DNA that may contain one or a plurality of donor plant genes. It is also unclear what the criteria are for “selectively propagating”. Applicant needs to state how transgenic plants will be selected.

Claim 25 is indefinite for reciting “high molecular weight”. This is a relative term and does not state the metes and bounds of the size fraction of the genomic DNA.

Claim 28 is indefinite for reciting “a cereal”. It is not clear from this expression which plants are included as the term has multiple meanings. Applicant is advised to specifically state the plants encompassed in the invention.

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 305-3015.

Stuart Baum Ph.D.

April 5, 2002

ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1800

